

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: PHILIPS RECALLED CPAP,
BI-LEVEL PAP, AND MECHANICAL
VENTILATOR PRODUCTS,
LITIGATION**

Master Docket No. 21-mc-1230-JFC

MDL No. 3014

This Document Relates to: All Actions

**SPECIAL DISCOVERY MASTER’S REPORT AND RECOMMENDATION AND PROPOSED
ORDER RE: DISCOVERY OF MEDICAL MONITORING NAMED PLAINTIFFS’ MEDICAL
HISTORIES AND PREVIOUS EXPOSURES TO HAZARDOUS SUBSTANCES**

I. INTRODUCTION

Plaintiffs Consolidated Second Amended Class Action Complaint for Medical Monitoring (“MMSCA”) (Doc. No. 815), asserts under various states’ laws that, because of the increased risk of serious disease caused by their exposure to hazardous toxins from the Recalled Devices’ PE-PUR foam (“Foam”), Defendants should be required to fund medically necessary diagnostic testing. The serious diseases for which Plaintiffs seek monitoring are: cancer, including cancer of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue, respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; chronic sinusitis, chronic rhinitis, and other forms of chronic inflammation. Plaintiffs also allege their exposure to toxins from the Foam causes widespread damage to DNA as well as reproductive, neurological, and other critical systems (referred to collectively as “Pleaded Conditions”). MMSCA ¶ 371.

Defendants posed discovery requests to named Plaintiffs about their medical histories and previous exposures. Plaintiffs agreed to produce only medical records from health care providers (“HCPs”) who prescribed the Recalled Devices, and only for the past five (5) years. Defendant Philips RS North America LLC (“Philips” or “Defendant”) seeks to compel responses to many of the remainder of their requests. The parties also disagree about the process for production of Plaintiffs’ medical records.

The interrogatories (“Rogg”) and Requests for Production of Documents (“RFP”) at issue fall into these basic categories: (1) Recalled Device related; (2) other medical conditions and monitoring; (3) other risk factors; (4) health insurance; and (5) the difference between the medical monitoring sought and that normally recommended. More specifically:

Request No.	Summary of Request ¹
RELATED TO RECALLED DEVICES	
Rogg 1(f)	Identify the reasons or conditions that led to the Recalled Device prescription
RFPs 2, 5, 6 & 8	HCP and DME (Durable Medical Equipment suppliers) documents related to prescriptions for or acquisition of the Recalled Device, and records from treating HCPs for any condition related to use of the Recalled Device
Rogg 6	Advice received to change use of the Recalled Device, including after the recall
PRIOR MEDICAL HISTORY GENERALLY	
Rogg 11 & RFP 40	Identify all medical monitoring, including frequency, nature, and reasons, and produce corresponding documents (5 years)
Rogg 12	Identify HCPs who provided regular check-ups or diagnostic tests or screening, with the nature of the service each provided (10 years)
Rogg 2.17	Identify (with names and addresses) all consulting and treating HCPs for any reason except mental health, with dates and reasons (10 years)
Rogg 13	Identify all diagnosed medical conditions and injuries excluding mental health, with medications and/or treatments and whether related to use of a Recalled Device (10 years)
RFP 22	Documents re: treatment or testing prescribed for any Pleaded Condition (10 years)
RFP 26	Documents re: diagnosed medical conditions and injuries excluding mental health (10 yrs.)
RFP 27	Documents that depict or refer to present conditions, injuries and/or damages

¹ These summaries are paraphrased for the sake of brevity, and listed in logical (rather than numerical) order. Where Philips RS agreed to modify an interrogatory or document request, this chart reflects the modified version. Where the request is limited to a specified time frame, that time frame is noted in parentheses. This list does not include additional requests Philips RS concedes are duplicative and therefore mooted, that is, Document Request Nos. 2, 7, 12, 15, 17, 19 and 34.

Rogg 2.19 & RFP 42	Identify employers through which sought workers compensation (with details about employment), and produce corresponding documents (10 years)
OTHER RISK FACTORS	
Rogg 14	Tobacco use, with frequency, when started, and (if applicable) when stopped (5 years)
Rogg 15	Family history of cancer or lung/respiratory disease (family defined as biological parents, siblings, grandparents, aunts and uncles)
Rogg 16	List of occupation(s) (20 years)
Rogg 17	Prior heightened exposure to chemicals or toxins at workplace or residence (20 years)
HEALTH INSURANCE	
Rogg 2.18 & RFP 41	Identify health insurance carriers (with policy number, policyholder and dates), and produce corresponding documents (10 years)
HOW MONITORING DIFFERS FROM NORM	
Rogg 2.20	Describe how the monitoring procedures being sought differ (in type, timing, frequency and scope) from what would normally be recommended absent the Foam exposure

THE PARTIES' POSITIONS

Plaintiffs assert they have not put their medical histories or risk factors at issue and therefore have not waived their physician-patient privilege concerning their past or present medical conditions. They view their medical monitoring claim as predicated solely on exposure to a known hazardous substance caused by Defendants' tortious conduct, not preexisting exposure, medical history, or family history.

Philips RS argues Plaintiffs' prior medical conditions, monitoring, and risk factors are at the center of their medical monitoring claims because they are relevant to whether they: (1) are already being screened, monitored, or treated for the illnesses or conditions they claim to be at risk for in the future because of exposure to the Foam; (2) are at risk of developing the Pleaded Conditions independent of their Recalled Device use; and (3) already have the Pleaded Conditions independent of their use of the Recalled Devices.

With regard to the process for producing medical records, Plaintiffs insist on collecting the documents, reviewing them (for example, for unresponsive sensitive or privileged

information), redacting and logging any redactions, and then producing the records. Philips RS wants Plaintiffs to provide medical authorizations so it can collect the documents itself.

II. DISCUSSION

A. Relevance and Proportionality

Under Rule 26(b)(1) of the Federal Rules of Civil Procedure, parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.

Jurisdictions recognizing a medical monitoring cause of action generally require plaintiffs to prove: (1) exposure to greater than normal background levels (2) of a proven hazardous substance (3) caused by defendant's negligence (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of exposure; and (vii) the prescribed monitoring procedure is reasonably necessary according to contemporary scientific principles. 1 *McLaughlin on Class Actions* § 5:18 (19th ed.). *See, e.g., Redland Soccer Club Inc. v. Dep't of the Army and Dep't of Def. of the U.S.*, 548 Pa. 178, 195, 696 A.2d 137, 145 (1997) (establishing these elements for a medical monitoring claim in Pennsylvania).²

As a matter of common sense, the fourth test prong – whether a plaintiff has a significantly increased risk of contracting a serious disease as a proximate result of the exposure

² Philips RS contends a number some states also require proof of present physical injury, which would directly implicate some of Plaintiffs' medical records. Plaintiffs disagree. Whether or not proof of present physical injury is required would not change the analysis below.

(“the causation element”) – renders some of Plaintiffs’ medical history potentially relevant.³ Medical conditions that pre-existed a Plaintiff’s Foam exposure would be relevant to whether that exposure “substantially increased” their future risk of a serious disease. For example, if a plaintiff already was being treated for a serious respiratory disease or terminal lung cancer, that would be relevant to whether their risk of a serious disease was “substantially increased” by exposure to the Foam. A Plaintiff’s prior exposures to other hazardous substances likely would be probative of that same question. And, the extent to which a Plaintiff’s HCP has advised monitoring for a Pleaded Condition would be relevant to determining if they are already undergoing monitoring duplicative of that they seek to have Philips RS fund.

Some discovery into Plaintiffs’ medical histories is therefore relevant. However, the private nature of a person’s medical history dictates the need to tailor discovery requests to avoid intruding into aspects of Plaintiffs’ medical histories that are not relevant.⁴

Plaintiffs do not cite one case barring all discovery of a medical monitoring plaintiff’s medical history. Instead, they rely solely on the prongs of the liability test that focus on the defendant’s conduct, and ignore the others, including the causation element.

In contrast, Philips RS cites a number of cases allowing at least *some* such discovery. Of note, though, some cases limited its scope. And, when addressing document requests for medical records, some required a two-step process – first interrogatories and then, if those uncover prior medical history germane to the litigation, tailored follow-up document requests.

³ The sixth prong – whether the prescribed monitoring regime is different from that normally recommended in the absence of exposure – likewise would implicate a plaintiff’s medical records to the extent this prong refers to recommendations normal for the plaintiff, as opposed to the general public.

⁴ The existence of a Protective Order in this case does not obviate the need to adhere to Rule 26(b)(1)’s guideposts of relevance and proportionality.

Brown v. Saint-Gobain Performance Plastics Corp., No. 16-cv-242-JL, 2018 WL 10517306, at *2-3 (D.N.H. Oct. 10, 2018), addressed the plaintiffs’ motion for a protective order relating to requested production of their medical, employment, and workers compensation records. The court held the plaintiffs’ medical monitoring claim placed their medical histories at issue and allowed for some, but not all, of the requested medical discovery. In so holding, the court relied on several decisions from other courts ordering plaintiffs in medical monitoring actions to produce some portion of their medical history (these cases are discussed below), and noted that the plaintiffs had offered no contrary authority.

The court deemed the defendant’s requests to be “overbroad to the extent that they seek production of all of the named plaintiffs’ medical, insurance, medication, and workers compensation records without any limitations on time and scope.” *Id.* at *2. The court narrowed the requests to require the plaintiffs to provide the identities of their medical providers, medications, and medical records for the prior 19 years, employment history, and workers compensation records. The court recognized these records might reveal a reasonable basis to believe other medical or employment records would have relevant information, in which case the defendant could follow up with additional requests.

Sullivan v. Saint-Gobain Performance Plastics Corp., No. 5:16-cv-125, 2017 WL 11508079 (D. Ver. 2017), at *4-5, was a groundwater pollution case arising out of the alleged discharge of perfluorooctanoic acid (PFOA) from the defendant’s factories. The defendant filed a motion to compel the production of medical, employment, and workers compensation records. In granting that motion in part, the court explained (*id.* at *4):

Both sides are permitted to develop their case in their own way . . . [T]he defense is not required to take the plaintiffs’ word for it concerning common elements of exposure and causation. The class representatives serve the function of being a sample of the class

members as a whole. An inquiry into other potential sources for the elevated PFOA is fair. Again, the court expresses no opinion about whether other sources of PFOA contamination are likely to be present. But the defense cannot be precluded from looking.

The court went on to consider the scope of the requests, and found them to be excessive. The court addressed that overbreadth in two ways: (1) by narrowing them; and (2) by keeping the door open to additional follow-up requests should the plaintiffs' responses reveal a reasonable basis to believe other doctors or hospitals had information about potential exposure to toxins or treatment for conditions related to PFOA exposure. Accordingly, the court ordered the plaintiffs to: (1) produce records of (only) their primary physicians for the prior 20 years; (2) answer interrogatories about their employment histories; and (3) answer interrogatories about any workers compensation claims and produce those records.

Ballard v. Union Carbide Corp., No. 2:11-cv-00366, 2012 WL 2089511, at *3-4 (S.D. W.Va. June 8, 2012), involved alleged exposure to substances emitted from a metals plant. The plaintiffs sought medical monitoring for cancer, diabetes, hypertension, severe respiratory damage, Parkinson's disease, mental retardation, and neurotoxic disorders. The court granted the defendant's motion to compel in part. It required the plaintiffs to answer interrogatories: (1) to identify each medical, psychiatric or psychological condition they had throughout their lives (with dates, descriptions, the HCPs consulted, among other details) and provide various details about each HCP or facility they consulted for diagnosis or treatment of the identified conditions; (2) to provide information about their use of tobacco products, alcohol, prescription and non-prescription medications and/or illegal drugs or other controlled substances; and (3) to describe family or personal history of illness or genetic disease, including any they claimed to be at significantly increased risk for because of the alleged exposure to the substances of concern.

(The court did not discuss any requests for medical records; apparently the motion to compel did not relate to document requests.)

Fiorentino v. Cabot Oil & Gas Corp., No. 3:09-cv-2284, 2011 WL 5239068, at *7-8 (M.D. Pa. Nov. 1, 2011), involved 62 plaintiffs alleging various causes of action relating to the defendants' operation of natural gas wells. Thirty-eight plaintiffs who asserted medical monitoring claims, but not personal injury claims, refused to produce medical records. The court disagreed, and ordered the plaintiffs to provide the defendants with medical authorizations for their medical records, and produce all responsive documents and information sought regarding their medical conditions, histories and providers.

O'Connor v. Boeing N. Am., Inc., 185 F.R.D. 272, 283 (C.D. Cal. 1999), involved a medical monitoring claim arising out of the release of alleged hazardous substances from the defendants' facilities. The defendants argued medical records for any illness were relevant since the plaintiffs' medical conditions are risk factors other than the exposure to the defendants' chemicals. The court agreed, and compelled production of the plaintiffs' medical records.

Again, simply because Plaintiffs' have put at issue their pre-existing risk of, or experience with, the Pleded Conditions, that does not mean Philips RS is entitled to their entire medical histories. While Philips RS narrowed a number of its requests, both temporally and otherwise, some are still too attenuated. Also, and importantly, Defendant wishes to collect all of Plaintiffs' medical records over the past 10 years – even those unrelated to use of the Recalled Devices or treatment for a Pleded Condition – rather than wait to see what Plaintiffs' interrogatory responses reveal about their medical histories, and then posing additional tailored requests. This approach would require a Plaintiff who has no relevant medical history, or who only undergoes normal, routine medical monitoring (such as annual mammograms), to produce *all* of their

medical records for the past 10 years. Instead, consistent with the approach taken in *Brown* and *Sullivan*, medical discovery should initially be limited to gathering: (1) information and documents that are highly likely to be relevant, such as requests directly related to the Recalled Devices or Pleaded Conditions, and (2) general medical history information through interrogatories that then will allow for additional follow-up requests customized to that which actually is relevant.

B. Recommended Rulings on Specific Discovery Requests

Applying the principles above to the disputed discovery requests, this Discovery Special Master recommends the Court rule as follows:

Recalled Device Related. The Recalled Devices are at the heart of this case, and may well be associated with pre-existing respiratory conditions. This is the one category Plaintiffs acknowledge is discoverable, but they seek to limit their responses to the past five years. Such a cutoff would be arbitrary, as the lawsuit involves all Recalled Devices, regardless of when they were prescribed or acquired. Accordingly, Defendant's motion to compel should be **granted** as to Interrogatories 1(f) and 6, and Requests for Production of Documents 2, 5, 6, and 8.

Past Medical Conditions and Monitoring. Philips RS's motion to compel should be **granted** as to Interrogatories 11 (other medical monitoring), 12 (HCPs who provide regular check-ups and screenings), 13 (diagnosed conditions), 2.17 (consulting and treating HCPs) and 2.19 (workers compensation claims) as narrowed.⁵ Defendant's motion should also be **granted** as to Document Request 22 (treatment or testing for the Pleaded Conditions), as any prior

⁵ Although mental health history is the only explicit exclusion Philips RS included in these discovery requests, the parties recognized in meet and confers there may be other highly sensitive and private conditions that are not relevant in this case, and agreed to address those in good faith as they arise.

treatment or monitoring for the diseases Plaintiffs have placed at issue in this case would likely be relevant. Philips RS's motion should be **denied without prejudice** as to document requests that ask for general medical history, that is, Requests for Production of Documents 26 (other diagnosed medical conditions), 27 (present conditions, injuries or damages), 40 (medical monitoring), and 42 (workers compensation claims) – to the extent Plaintiffs' interrogatory responses reveal pre-existing conditions or monitoring that would bear on their medical monitoring claim, Philips RS may propound tailored follow-up document requests (these additional targeted requests should not count against Defendant's discovery limits).

Other Risk Factors. Defendant's motion to compel should be **granted** as to Interrogatories 14-17 about risk factors other than the Foam, such as tobacco use, family medical history, occupational risks and prior exposures to hazardous substances.

Health Insurance. Defendant's motion to compel should be **denied** as to Interrogatory 2.18 and Document Request 41. None of the cases Philips RS cites support the need for detailed health insurance information. Defendant argues insurance information may reveal coverage for screening, monitoring and/or treatment that a Plaintiff declined. This argument is far-fetched. Through the two-step process contemplated above, Defendant will receive relevant medical records. A Plaintiff's insurance coverage is highly unlikely to add any material insights, or to be worth the effort to gather that information and related documentation.

Monitoring Sought. Philips RS's motion to compel a response to Interrogatory 2.20 should be **denied**. Plaintiffs will rely on medical experts to prove how the medical monitoring they seek differs from what would normally be recommended. Plaintiffs' opinion on this score is not relevant, as their only basis to respond (if they can at all) would be to speculate or to repeat an expert's advice.

C. Process for Production of Medical Records

Plaintiffs may choose to provide authorizations to Defendant's counsel to ease their burden, but they should not be required to do so. In connection with its document productions, Philips RS took the opportunity to review documents for responsiveness and privilege before producing them to Plaintiffs, and Plaintiffs should be afforded the same opportunity, especially because there may be highly sensitive medical information (other than mental health history, which Philips RS excluded) that is irrelevant to this case. Philips RS's counsel is concerned Plaintiffs will not produce the medical records timely, and this will compromise their ability to comply with discovery and expert deadlines. If Plaintiffs fail to timely produce medical records, then Philips RS may raise that problem and it will be addressed at that time.

III. CONCLUSION

For the reasons set forth above, the Special Discovery Master recommends that Philips RS's Motion to Compel be **GRANTED IN PART** and **DENIED IN PART** as set forth in the attached Proposed Order.

Date: November 13, 2023

Respectfully submitted by:

A handwritten signature in blue ink that reads "Carole Katz". The signature is written in a cursive, flowing style.

Carole Katz (PA Id. No. 43911)
Special Discovery Master

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**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: PHILIPS RECALLED CPAP,)
BI-LEVEL PAP, AND MECHANICAL)
VENTILATOR PRODUCTS,)
LITIGATION)**

Master Docket No. 21-mc-1230-JFC

MDL No. 3014

This Document Relates to: All Actions

[PROPOSED] ORDER

AND NOW, this ____ day of _____, 2023, it is hereby **ORDERED** that Philips RS's Motion to Compel be **GRANTED IN PART** and **DENIED IN PART** as follows:

The Motion is **GRANTED** as to Interrogatory Nos. 1(f), 6, 11-17, 2.17, and 2.19 and Requests for Production of Documents Nos. 2, 5, 6, 8, and 22. To the extent Plaintiffs' counsel believes responsive information or documents will reveal highly sensitive medical history that is not relevant, they shall meet and confer and, if necessary, engage the Discovery Special Master.

The Motion is **DENIED** as to Interrogatory Nos. 2.18, and 2.20, and Request for Production of Documents No. 41.

The motion is **DENIED WITHOUT PREJUDICE** as to Requests for Production of Documents Nos. 26, 27, 40, and 42. Defendant may propound narrowed versions of these Requests to seek relevant documents based on Plaintiffs' responses to interrogatories. These additional follow-up requests will not count against any applicable numerical limits to permitted document requests.

Joy Flowers Conti, Judge

CERTIFICATE OF SERVICE

I hereby certify that on the 13th of November, 2023, I electronically filed the foregoing Special Discovery Master's Report and Recommendation and Proposed Order re: Discovery of Medical Monitoring Named Plaintiffs' Medical Histories and Previous Exposures to Hazardous Substances, using the CM/ECF system which will send notification of such filing to all counsel of record.

A handwritten signature in blue ink that reads "Carole Katz". The signature is written in a cursive, flowing style. The "C" is large and loops around the "a", and the "K" has a long, sweeping tail that extends under the "z".

Carole Katz, Special Discovery Master